## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Name of the Finished Pharmaceutical Product

### 1.1 Proprietary Name

LOREZE

### 1.2 Strength

Each soft gelatin capsule contains: Loratadine micronized 10mg.

### 1.3 Description

Clear yellowish, liquid filled in 6 minim, oval, blue transparent soft gelatin shell capsules.

### 2. Qualitative and Quantitative Composition

### 2.1 Qualitative Declaration

| **Active ingredient** | **Grade** |
|---|---|
| Loratadine micronized | EP Current Edition |
| **In- active ingredients** | |
| Polyethylene glycol 400 | EP Current Edition |
| Propylene glycol | USP Current Edition |
| Polysorbate 80 | USP Current Edition |
| **Capsule shell ingredients** | |
| Gelatin lime bovine 160 bloom (DGF) | EP Current Edition |
| Glycerin | EP Current Edition |
| Purified water | EP Current Edition |
| Brilliant blue | In-house |

'For full list of excipients, see section 6.1

### 2.2 Quantitative Declaration

| **Active ingredient** | **Quantity/ Capsule (mg)** |
|---|---|
| Loratadine micronized | 10.0000 |
| **In- active ingredients** | |
| Polyethylene glycol 400 | 108.0000 |
| Propylene glycol | 16.0000 |
| Polysorbate 80 | 162.0000 |
| **Capsule shell ingredients** | |
| Gelatin lime bovine 160 bloom (DGF) | 17.5580 |
| Glycerin | 56.2235 |
| Purified water | 7.3500 |
| Brilliant blue | 0.1833 |

## 3. Pharmaceutical Form

Capsules, Soft Gelatin..

## 4. Clinical Particulars

### 4.1 Therapeutic Indications

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- Runny nose

- Sneezing

- Itchy, watery eyes

- Itching of the nose or throat

- Symptomatic relief of pruritus, erythema and urticaria associated with chronic idiopathic urticaria.

### 4.2 Posology and method of administration

Adults and children 6 years of age and older: 1 capsule daily or as directed by a physician.
Method of Administration: Oral

### 4.3 Contraindications

Hypersensitivity or intolerance to any component of product.

### 4.4 Special Warnings and Precautions for Use

Patients with hepatic impairment or renal insufficiency (e.g. glomerular filtration rate less than 30 mL/minute), including geriatric patients, have decreased clearance of the drug, and should be given a lower initial dose of Loratadine.

Patients should be advised to discontinue loratadine therapy immediately and to contact their doctor if any signs of an allergic reaction occur.

### 4.5 Interaction with other medicinal products and other forms of interaction

Although increased plasma concentrations of loratadine and its active metabolite desloratadine have been reported when the drug was concomitantly administered with therapeutic dosages of ketoconazole, erythromycin, clarithromycin, or cimetidine in controlled clinical pharmacology studies in healthy individuals, no clinically important changes in electrocardiogram or laboratory evaluations, vital signs, or adverse effects were reported.

### 4.6 Use in pregnancy and lactation

Because there are no adequate and controlled studies to date using loratadine in pregnant women, loratadine should be used during pregnancy only when the potential benefits justify the possible risks to the fetus.

Loratadine and desloratadine distribute readily into breast milk, achieving concentrations that are equivalent to those in plasma. Caution should be exercised when loratadine is administered to a nursing woman.

**4.7 Effects on ability to drive and use machines**

Loreze has influence on ability to drive and use machines. Sedation (e.g. drowsiness, fatigue) occurred in about 12% (e.g. 8 and 4% respectively) of patients receiving loratadine in clinical trials. The incidence of drowsiness appears to be dose related; although the incidence of drowsiness in patients receiving 10 mg of loratadine is no greater than that in patients receiving placebo, dose-related drowsiness becomes more prominent with doses of 20 - 40 mg.

**4.8 Undesirable Effects**

The most frequent adverse effects reported with loratadine are nervous system effects. Adverse nervous system effects occurring in at least one pediatric or adult patient receiving loratadine in clinical trials include hypoesthesia, asthenia, dizziness, dysphonia, hypertonia, migraine, paresthesia, tremor, vertigo, agitation, amnesia, anxiety, confusion, decreased libido, depression, impaired concentration, irritability, morbid dreaming, headache and sedation.

**4.9 Overdose**

The acute lethal dose of loratadine in humans is not known. In adults, drowsiness, tachycardia, and headache have been reported after overdoses (e.g. 40-180 mg) of loratadine tablets. Treatment of loratadine overdosage generally involves symptomatic and supportive care, initiated promptly and maintained as long as necessary. In acute loratadine overdosage, the stomach should be emptied immediately by inducing emesis with ipecac syrup. Administration of activated charcoal after emesis may be useful in preventing absorption of loratadine.

**5. Pharmacological properties**

**5.1 Pharmacodynamic Properties**

Loratadine is a long-acting antihistamine. The drug has been characterized as a specific, selective peripheral H1-receptor antagonist and has been referred as a second-generation antihistamine.

**5.2 Pharmacokinetic Properties**

Loratadine is rapidly absorbed from the GI tract following oral administration. Following oral administration of a single 10-mg dose of loratadine in healthy adults, mean peak plasma concentrations of 4.7 and 4 ng/ml of the drug and its active metabolite desloratadine were attained in about 1.5 and 3.7 hours, respectively.

Following oral administration of loratadine, the antihistaminic effect of the drug is apparent within 1-4 hours, and the onset of antihistamic action appears to correlate with rapid absorption of loratadine and formation of desloratadine.

Distribution of loratadine and its metabolites into human body tissues and fluids has not been determined. Large clearance values following oral administration of loratadine suggest extensive presystemic metabolism and/or tissue distribution of the drug in humans.

The mean distribution half-life of unchanged loratadine was about 1-2 hours, and the mean elimination half-life was 8-15 hours; the mean distribution halflife of desloratadine was 2-4 hours, and the mean elimination half-life was about 17-28 hours. Plasma clearance of loratadine is high after oral administration, probably secondary to extensive first-pass metabolism and tissue distribution. Loratadine undergoes extensive first-pass metabolism, and is metabolized in the liver by the cytochrome P-450 (CYP) microsomal enzyme system, principally by hydrolysis of the carbamate moiety to the active metabolite desloratadine.

After 10 days of daily administration of loratadine, about 80% of the drug is excreted as metabolic products equally distributed in urine and feces.

**5.3 Preclinical Safety Data**

Not applicable.

## 6. Pharmaceutical Particulars

### 6.1 List of Excipients

Polyethylene glycol 400, polysorbate 80, propylene glycol, gelatin, glycerin, brilliant blue and purified water.

### 6.2 Incompatibilities

None.

### 6.3 Shelf Life

Two years from manufacturing date.

### 6.4 Special Precautions for Storage

Store below 25°C in a dry place, away from direct sunlight.

### 6.5 Nature and Contents of Container

Unit carton containing 5x10 capsules blister-packed.

### 6.6 Special precaution for disposal and other handling

No special requirements.

## 7. Marketing Authorization Holder and Manufacturing Site Addresses

**MEGA LIFESCIENCES Public Company Limited**

384 Moo 4, Soi 6, Bangpoo Industrial Estate,

Pattana 3 Road, Phraeksa, Mueang,
Samutprakarn 10280, Thailand.

## 8. Marketing Authorization Number

## 9. Date of first Registration/ Renewal of the Registration

## 10. Date of revision of the text